

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

<p>SANDOZ, INC., <i>et ano.</i>,</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>UNITED THERAPEUTICS CORP., <i>et ano.</i></p> <p style="text-align: center;">Defendants.</p> <hr/>	<p>Civil Action No.: 19-10170</p> <p style="text-align: center;"><b>OPINION AND ORDER OF THE SPECIAL DISCOVERY MASTER REGARDING DEFENDANT’S MOTION TO ADD FOUR DOCUMENT CUSTODIANS</b></p>
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**LINARES, J.**

This matter comes before the Special Master by way of Defendant’s Motion to Add Four Additional Document Custodians (“Def. Br.”), which was submitted on December 23, 2020. Plaintiffs Sandoz and RareGen both submitted Oppositions to Defendant’s Motion (“Sandoz Opp.” and “RareGen Opp.”, respectively) on January 7, 2021. Defendant submitted a brief Reply to Plaintiffs’ Oppositions on January 14, 2021 by way of email. The Special Master has reviewed the submissions and the relevant controlling law, and for the reasons set forth below hereby **GRANTS** Defendant’s Motion.

## **I. FACTS**

The Special Master presumes the parties' familiarity with the facts and procedural posture of this matter. As such, the Special Master will only recite the facts pertinent to the subject dispute.

Based on the discovery exchanged to date, Defendant proposes adding four document custodians; three from Plaintiff Sandoz and one from Plaintiff RareGen. (*See generally* Def. Br.). Specifically, Defendant asks that Ms. Carol Lynch ("Lynch")<sup>1</sup>, Mr. Craig Osten ("Osten")<sup>2</sup>, and Mr. Mike Fraser ("Fraser")<sup>3</sup> from Sandoz be added as document custodians. (Def. Br. at 1). Additionally, Defendant also requests that Mr. Paul Manning ("Manning")<sup>4</sup> from Plaintiff RareGen be added as well. (Id.).

Lynch is the President of Sandoz U.S., and, Defendant asserts, is the equivalent of Defendant's President Michael Benkowitz, who is already a document custodian in this action. (Id. at 3). Osten is Plaintiff Sandoz's Chief Financial Officer, and Fraser is Plaintiff Sandoz's Vice President for Strategy and Innovation. (Id. at 7). Finally, Manning is one of Plaintiff RareGen's three founding directors. (Id. at 6).

Defendant outlines specific reasons why each of these individuals should be added as a document custodian. The Special Master discusses each request separately below.

## **II. LEGAL STANDARD**

Rule 26 governs discovery demands, including those that relate to document custodians. *See* Fed. R. Civ. P. 26. Subsection (b)(1) provides that "[p]arties may obtain discovery regarding

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<sup>1</sup> Defendant asks that Lynch's custodial file encompass any and all relevant, nonprivileged documents from March 2018 to present.

<sup>2</sup> Defendant asks that Osten's custodial file encompass any and all relevant, nonprivileged documents from June 2018 to present.

<sup>3</sup> Defendant asks that Fraser's custodial file encompass any and all relevant, nonprivileged documents from April 2018 to present.

<sup>4</sup> Defendant asks that Manning's custodial file encompass any and all relevant, nonprivileged documents from January 2018 to present.

[] nonprivileged matter[s] that [are] relevant to any party’s claim or defense and proportional to the needs of the case.” *Id.* at (b)(1). Any party objecting to a discovery demand must show that the demand is not relevant and/or is disproportionate to the needs of the case. *See Baier v. Princeton Office Park, L.P.*, 2018 WL 5253288, at \*4 (D.N.J. Oct. 22, 2018).

### III. ANALYSIS

Defendant advances a general theory that is applicable to each of the proposed document custodians. (Def. Br. at 2-3). Specifically, Defendant believes that the information gathered from the four proposed document custodians will shed light on Plaintiffs’ decision to launch its generic version of treprostinil before it secured a subcutaneous delivery method. (*Id.*). Defendant goes on to showcase how each of the proposed document custodians likely has additional information that will provide insight on Plaintiffs’ decision to launch the generic drug. (*See generally* Def. Br.)

#### Lynch

As noted, Lynch is the President of Plaintiff Sandoz U.S. (*Id.* at 3). Defendant presents various indications that Lynch, at least in part, was involved in the decision to launch the generic treprostinil as an “IV-only” drug. (*Id.* at 4). Based on the discovery exchanged to date, Defendant asserts Lynch pressured junior members of the Sandoz team to launch treprostinil in the first fiscal quarter of 2019 and had ongoing conversations with Plaintiff RareGen’s Manning regarding same. (*Id.*). Moreover, Defendant points to the fact that Lynch was also involved in discussions with one of the specialty pharmacies, Accredo, to discuss the treprostinil launch. (*Id.*).

These items of evidence, Defendant avers, indicate that Lynch did have a part in the decision making process as it related to how and when Plaintiff Sandoz launched its generic

treprostinil. Defendant goes on to argue that obtaining Lynch's custodial file will allow Defendant to fully explore and understand Lynch's role in Plaintiff Sandoz's decision to roll out an "IV-only" version of treprostinil. (Id.).

The Special Master agrees with Defendant. While Plaintiff Sandoz does raise a meritorious opposition, that being that Defendant has presented very little to show Lynch's connection to the decision to launch in early 2019 (Sandoz Opp. at 5-7), the connection exists nonetheless. Indeed, Defendant has provided just enough information that would leave a reasonable person wondering whether Lynch was actually more involved in the launch of generic treprostinil. That curiosity warrants allowing Defendant to explore Lynch's involvement in the launch. Such an exploration begins with reviewing Lynch's custodial file. Therefore, the Special Master grants Defendant's request to add Lynch as a document custodian.

*Osten and Fraser*

Defendant discusses Osten and Fraser simultaneously, and, as such, the Special Master will dispose of the request pertaining to these two individuals in the same manner. As to Osten, Defendant notes that he was, and remains, the Chief Financial Officer of Plaintiff Sandoz. (Def. Br. at 7). As such, Defendant avers that, based on the discovery received to date, Osten was investigating financial incentives of, and effects of key developments from, the generic treprostinil launch. (Id.). Defendant also points to emails where Osten was advocating the "IV-only" launch. (Id.). Once again, Defendant avers there is enough trace evidence to warrant further investigation.

As to Fraser, Defendant makes nearly the same argument, but based on different facts. According to Defendant, "Fraser was directly involved in the decision to launch IV Only." (Id.). Defendant arrives at this conclusion by pointing to a specific email where Fraser asked Plaintiff

Sandoz's Senior Executive Committee to "prioritize" the generic treprostinil launch. (Id. (quoting SANDOZ\_Trep\_00038685)). Moreover, Plaintiff Sandoz semi-concedes that Fraser's custodial file may be relevant. (See Sandoz Opp. at 8 ("Of the three requested custodians, Fraser is the only one for which there is even a colorable argument for adding. In his role as VP for Strategy and Innovation, *Fraser had some supervisory role over the treprostinil launch.*") (emphasis added)).

In light of the above, the Special Master concludes that both Osten and Fraser should be added as document custodians. Indeed, just as with Lynch, Defendant has set forth sufficient pieces of evidence that warrant further exploration. With regard to Osten, Defendant has highlighted small bits of evidence that show he was, in some capacity, monitoring the launch of treprostinil from a financial capacity. Hence, it is not farfetched, as Plaintiff Sandoz argues, to infer that Osten was also involved in conversations revolving around the decision to launch generic treprostinil as IV-only and in early 2019.

The same is true for Fraser. Defendant has submitted, albeit minimal, sufficient evidence such that an inquisitive mind is left wondering the extend of Fraser's involvement and influence in the generic drug's launch. Indeed, even Plaintiff Sandoz has conceded this fact. Hence, Fraser's supervisory role over the launch is a sufficient reason to allow Defendant to review Fraser's custodial file.

Accordingly, the Special Master finds that Defendant has made a successful argument in favor of adding Osten and Fraser as document custodians, and grants Defendant's request as to these two individuals.

Manning

Finally, Manning is one of Plaintiff RareGen's founders. Manning has produced some documents, but only through his investment firm, PBM Capital. (RareGen Opp. at 1). Moreover, the production was only for the first three months of 2019; the three months leading up to the launch. (Id.).

Defendant argues that Manning should be personally listed as a document custodian as he was actively involved in the decision to launch generic treprostinil. (Def. Br. at 6). First, Defendant notes that the current list of document custodians from RareGen are individuals who only dealt with operational issues and not the decision to launch. (Id.). Furthermore, Defendant points to various emails where Manning is promoting the launch and trying to expedite it. (Id. (quoting RareG0076081 ("Launch next week come on"); RareG0076104 ("We should launch ASAP..."); RareG0083671 ("Shipping first week in January RIGHT") (emphasis in original))). Defendant asserts that these communications, along with Manning's position at Plaintiff RareGen, show that Manning was, in some way, actively involved in the decision to launch generic treprostinil in early 2019.

The Special Master is inclined to agree with Defendant. Indeed, Defendant has provided sufficient evidence tending to show that Manning did have some influence over the launch. Hence, Defendant is entitled to investigate Manning's involvement and to get a clear understanding of the circumstances surrounding the decision to launch the IV-only generic treprostinil. Accordingly, the Special Master grants Defendant's request as to Manning.

Proportionality

Plaintiff Sandoz argues that Defendant's request is disproportionate to the needs of this case. (Sandoz Opp. at 8-10). The Special Master disagrees. First, the Special Master notes that

a similar argument was raised by Defendant when Plaintiffs sought additional custodians. However, the Special Master was not persuaded by same given the magnitude of the claimed damages. (ECF No. 249 at 3-4, 6-9) Hence, the Special Master ordered Defendant to produce the custodial files demanded by Plaintiffs. Fairness and consistency warrants a similar outcome here.

As discussed at length above, Defendant has made a good faith showing as to why each individual should be a document custodian and how each person fits into its defense. Therefore, denying Defendant the opportunity to explore these meritorious avenues would be contrary to the spirit of Rule 26 and the broad and complete discovery it contemplates.

Finally, Plaintiffs have not presented the Special Master with any concrete evidence to support the position that the additional document custodians would be disproportionate to the needs of this case. For example, Plaintiffs have not advised the Special Master how many “hits” or documents would have to be reviewed and/or produced if the aforementioned individuals were added as document custodians. Nor have Plaintiffs described how long they estimate it will take them to review the custodial files for privilege. Rather, Plaintiffs merely make a broad statement of disproportionality. However, as noted above, it is Plaintiffs burden to convince the Special Master that the discovery demanded is not proportionate to the needs of the case; a burden Plaintiffs have not carried. Therefore, the Special Master rejects Plaintiffs’ proportionality argument.

#### **IV. ORDER**

For the foregoing reasons, it is on this 26th day of January 2021,

**ORDERED** that Defendant’s Motion to Add Four Document Custodians is hereby **GRANTED**; it is further

**ORDERED** that Plaintiff Sandoz shall produce Ms. Carol Lynch's entire nonprivileged custodial file from March 2018 to present within thirty (30) days of this Order; it is further

**ORDERED** that Plaintiff Sandoz shall produce Mr. Craig Osten's entire nonprivileged custodial file from June 2018 to present within thirty (30) days of this Order; it is further

**ORDERED** that Plaintiff Sandoz shall produce Mr. Mike Fraser's entire nonprivileged custodial file from April 2018 to present within thirty (30) days of this Order; and it is further

**ORDERED** that Plaintiff RareGen shall produce Mr. Paul Manning's entire nonprivileged custodial file from January 2018 to present within thirty (30) days of this Order.

**SO ORDERED.**

/s/ Jose L. Linares

Hon. Jose L. Linares, U.S.D.J. (Ret.)

Date: January 26, 2021